In the United States Patent and Trademark Office
Before the Board of Patent Appeals and Interferences

Appl. No.	:	10/544,151	Confirmation No. 6429
Applicant	:	Francis X. Smith et al.	
Filed	:	August 1, 2005	Art Unit: 1627
Title	:	L-HISTIDINE IN OPHTHALMIC SOLUTIONS	
Examiner	:	Fay, Zohreh A.	
Docket No.	:	3009108 US01	
Customer No.	:	44,331	

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REPLY BRIEF FOR APPLICANT PURSUANT TO 37 C.F.R. 41.41 AND 35 U.S.C. 1208

Sir:

Appellants hereby submit this reply brief to the Board of Patent Appeals and Interferences in response to the Examiners answer dated April 13, 2011.

I. Table of Contents

II. Real Party In Interest

The real party in interest is the assignee of the application, FXS Ventures, LLC, having a place of business in the city of Salem, New Hampshire.

III. Related Appeals and Interferences

An appeal to the Board of Patent Appeals in Interferences was filed in U.S. Pat. Appl. No. 11/613,029, which is a continuing application from this pending application, on January 6, 2011. To date, no decision has been rendered by a court or the Board.

IV. Status of the Claims

Claims 1-4 and 6-11 are pending in the application.

Claim 5 is cancelled.

Claims 1-4 and 6-11 are rejected.

Claims 1-4 and 6-11 are hereby appealed.

Appendix I provides a clean, double spaced copy of the claims on appeal.

V. Status of Amendments

A response after Final, including only remarks, was filed on November 29, 2010, subsequent to the Final Rejection. An Advisory Action dated December 13, 2010 was then received indicating that the Examiner considered, but did not find that the remarks were sufficiently persuasive to place the Application in condition for allowance. An Appeal Brief was filed on December 29, 2010 highlighting the errors in the prior rejection. An Examiner's answer was mailed April 13, 2011 maintaining the rejection.

VI. Summary of Claimed Subject Matter

The invention relates to a single-part ophthalmic solution, a single-part contact lens solution and a method for providing a single-part ophthalmic, the solution containing 0.001 to 10 weight percent of a simple saccharide (in particular embodiments the simple saccharide being inositol, mannitol, sorbitol, sucrose, dextrose, or glycerin) and at least 0.0001 weight to 10 weight percent polyhexamethylene biguanide, the solution being physiologically compatible with direct contact with corneal tissue and having improved preservative efficacy.

Independent claim 1 recites a contact lens solution (Para. [0005]) comprising 0.001 to 10 weight percent of a preservative enhancer (Para. [0006]) chosen from the group consisting of: inositol (Para. [0006]); mannitol (Para. [0006]); sorbitol (Para. [0006]); sucrose (Para. [0006]); dextrose (Para. [0006]); and glycerin (Para. [0006]); at least 0.0001 weight percent of polyhexamethylene biguanide (Para. [0007]); and where the concentration of chloride in said solution is less than 0.2 percent by weight (Para. [0006]); wherein said solution is an aqueous solution effective as a single-part solution (Para. [0029]); wherein said solution is physiologically compatible with direct contact with corneal tissue (Para. [0003]).

Independent claim 8 recites an ophthalmic solution (Para. [0005]) comprising 0.001 to 10 weight percent sorbitol (Para. [0006]), at least 0.0001 weight percent polyhexamethylene biguanide (Para. [0007]), and less than 0.2 weight percent chloride (Para. [0006]); wherein said solution is an aqueous solution effective as a single-part solution (Para. [0029]); wherein said solution is physiologically compatible with direct contact with corneal tissue (Para. [0003]).

Independent claim 9 recites a contact lens solution (Para. [0005]) comprising as a preservative enhancer 0.001 to 10 weight percent of a simple saccharide (Para. [0006]); and at least 0.0001 weight to 10 weight percent polyhexamethylene biguanide (Para. [0007]); wherein said solution is an aqueous solution effective as a single-part solution (Para. [0029]); wherein said solution is physiologically compatible with direct contact with corneal tissue (Para. [0003]).

Independent claim 11 recites a method for providing an ophthalmic solution (Para. [0005]) comprising: contacting an eye (Para. [0003]) with a single-part solution (Para. [0029]) comprising 0.001 to 10 weight percent of a preservative enhancer (Para. [0006]) chosen from the group consisting of: inositol (Para. [0006]); mannitol (Para. [0006]); sorbitol (Para. [0006]); sucrose (Para. [0006]); dextrose (Para. [0006]); and glycerin (Para. [0006]); at least 0.0001 weight percent of polyhexamethylene biguanide (Para. [0007]); and where the concentration of chloride in said solution is less than 0.2 percent by weight (Para. [0006]).

VII. Grounds of Rejection to be Reviewed on Appeal

The following issues were presented for review by the Board of Patent Appeals and Interferences:

1. Whether claims 1-4, 6-7 and 9-10 are unpatentable under 35 § U.S.C. 103(a) over Asgharian et al. (U.S. Patent No. 6,139,646).

2. Whether claim 8 is unpatentable under 35 § U.S.C. 103(a) over Asgharian et al. (U.S. Patent No. 6,139,646).

3. Whether claim 11 is unpatentable under 35 § U.S.C. 103(a) over Asgharian et al. (U.S. Patent No. 6,139,646).

VIII. Arguments

In addition to the arguments filed along with the Appeal Brief dated December 29, 2010, Applicant submits the following two remarks in response to the Examiner's answer mailed April 13, 2011.

First, the Examiner's answer indicates that Asgharian et al. indicates that the solutions are acceptable to the eye. However, this contention is in direct conflict with the information provided in the Declaration of Mr. Ed Jahngen, filed under 37 C.F.R. 132 and first submitted with the response dated April 12, 2010. While enzyme solutions may be used to clean a contact lens, caution should be taken to prevent the solution from directly contacting the eye. Enzyme solutions work by digesting the protein build up on the contact lens. Those same enzymes would also digest the natural proteins found in the eye should they come in contact. That is why enzyme solutions are rinsed away prior to putting a contact lens in ones eye. While Asgharian et al. does state that the solutions are "physiologically compatible" for use as storing, rinsing, cleaning and disinfecting solutions, enzyme solutions are not suitable for direct contact with corneal tissue as claimed. The fact remains that bringing enzyme solutions into contact with corneal tissue would cause severe damage. Even in the applied functions of storing, rinsing, cleaning and disinfecting, such enzyme solutions in use are rinsed away prior to placing a contact lens in contact with an eye to prevent the enzyme from digesting those healthy proteins naturally found in the eye. For this reason, along with the statements already on record, it is respectfully requested that the rejection be reversed.

Second, the Examiner indicates that "Part II" of the solution taught by Asgharian et al. may be used as either as stand-alone disinfecting solution or as a part II of a multi component solution. However, the reference, when read as whole, indicates that the enzyme is to the disinfection solution. Col. 12, Lns 1 – 27 indicate that the enzyme, whether as a liquid droplet or as a tablet, is added to the solvent or disinfectant solution prior to soaking the lens. Additionally, as discussed in detail in the Appeal Brief dated December 29, 2010, when reading Asgharian et al. as a whole, the reference is directed towards utilizing enzyme solutions. Each of the examples, the abstract and the claims indicate that the solution contains an enzyme solution. In addition to the explicit examples referenced above, Asgharian et al. labels the solution "Part II." By labeling a solution "Part II" it is generally understood that it is the second part of mixture containing

at least two parts. As such, the "Part II" solution of Asgharian et al. would be understood by one skilled in the art to be one component of a multi-component solution.

IX. Summary

Asgharian et al. does not teach or disclose a solution that is suitable for direct contact with corneal eye tissue. Instead, Asgharian et al. teaches the use of an enzyme solution. Enzyme solutions are known to digest proteins, including those proteins found naturally in the eye. Due to the dangers of placing enzyme solutions, even when cleaning a contact lens with an enzyme solution, it is required to first rinse away the solution prior to placing the contact in the eye. As such, enzyme solutions are not suitable for direct contact with corneal eye tissue.

When reading Asgharian et al. as a whole, it is understood that the "Part II" solution is meant to be one component of a multi-component solution. Separating out this component from the rest of the teachings of the reference is unsupported by the document alone and is therefore improper.

Therefore, for the reasons of record, it is respectfully urged that the rejection be reversed.

X. Conclusion

For the above reasons, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the rejection by the Examiner and mandate the allowance of claims 1 – 4 and 6 – 11.

Respectfully submitted,

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XI. Appendix I - Claims on Appeal

1. A contact lens solution comprising 0.001 to 10 weight percent of a preservative enhancer chosen from the group consisting of: inositol; mannitol; sorbitol; sucrose; dextrose; and glycerin; at least 0.0001 weight percent of polyhexamethylene biguanide; and where the concentration of chloride in said solution is less than 0.2 percent by weight; wherein said solution is an aqueous solution effective as a single-part solution; wherein said solution is physiologically compatible with direct contact with corneal tissue.

2. The contact lens solution of claim 1, wherein the concentration of said polyhexamethylene biguanide is between 1 and 100 parts per million.

3. The contact lens solution of claim 1, further comprising a physiologically compatible buffer selected from the group consisting of phosphate, bicarbonate, citrate, borate, ACES, BES, BICINE, BIS-Tris, BIS-Tris Propane, HEPES, TRIS, HEPPS, imidazole, MES, MOPS, PIPES, TAPS, TES, and Tricine.

4. The contact lens solution of claim 1, further comprising between 0.01 % and 5.0% glycerin.

5. (Cancelled).

6. The contact lens solution of claim 1 further comprising a wetting agent selected from the group consisting of polysorbate surfactants, polyoxyethylene surfactants, phosphonates, saponins and polyethoxylated castor oils.

7. The contact lens solution of claim 1 further comprising a sequestering agent selected from the group consisting as ethylenediaminetetraacetic acid, phosphonates, citrate, gluconate and tartarate.

8. An ophthalmic solution comprising 0.001 to 10 weight percent sorbitol, at least 0.0001 weight percent polyhexamethylene biguanide, and less than 0.2 weight percent chloride; wherein said solution is an aqueous solution effective as a single-part solution; wherein said solution is physiologically compatible with direct contact with corneal tissue.

9. A contact lens solution comprising as a preservative enhancer 0.001 to 10 weight percent of a simple saccharide; and at least 0.0001 weight to 10 weight percent polyhexamethylene biguanide; wherein said solution is an aqueous solution effective as a single-part solution;

wherein said solution is physiologically compatible with direct contact with corneal tissue.

10. The contact lens solution of claim 3, wherein said physiologically compatible buffer is selected from the group consisting of phosphate, bicarbonate, citrate,

ACES, BES, BICINE, BIS-Tris, BIS-Tris Propane, HEPES, HEPPS, imidazole, MES, MOPS, PIPES, TAPS, TES, and Tricine.

11. A method for providing an ophthalmic solution comprising:

contacting an eye with a single-part solution comprising 0.001 to 10 weight percent of a preservative enhancer chosen from the group consisting of: inositol; mannitol; sorbitol; sucrose; dextrose; and glycerin; at least 0.0001 weight percent of polyhexamethylene biguanide; and where the concentration of chloride in said solution is less than 0.2 percent by weight.

XII. Appendix II – Evidence

Declaration of Mr. Ed Jahngen, filed under 37 C.F.R. 132 and first submitted with the response dated April 12, 2010.

Appendix III – Related Proceedings

An appeal to the Board of Patent Appeals in Interferences was filed in U.S. Pat. Appl. No. 11/613,029, which is a continuing application from this pending application, on January 6, 2011. To date, no decision has been rendered by a court or the Board.